



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/553,923

10/21/2005

Catherine Allieux

30-000610US

1226

22798

7590

10/09/2007

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.

P O BOX 458

ALAMEDA, CA 94501

EXAMINER

YANG, NELSON C

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

10/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/553,923

Applicant(s)

ALLIOUX ET AL.

Examiner

Nelson Yang

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/14/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-21 in the reply filed on July 23, 2007 is acknowledged.

2. Claims 22 and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on July 23, 2007.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-6, 10-12, 15, and 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Monforte [US 7,091,046].

With respect to claim 1, Monforte teaches multiplexed assays for determining protein levels within a sample (column 2, lines 40-45), wherein the proteins are derived from one or more cells (column 2, lines 55-63). Monforte further discloses a binding moiety such as an antibody attached to a solid support that captures the target protein and a second binding moiety comprising a second antibody containing a signal generating element then binds to the captured

Art Unit: 1641

target protein (column 13, lines 55-65), wherein both antibodies may act as affinity reagents. The protein is then detected and quantitated (column 14, lines 1-8):

5. With respect to claim 2, the proteins may be derived from a cell lysate or a blood sample (column 2, lines 59-64), or from organs (column 14, lines 60-65).

6. With respect to claim 3, Monforte further discloses a binding moiety such as an antibody attached to a solid support that captures the target protein (column 13, lines 55-65), wherein the antibodies may be monoclonal or polyclonal (column 17, lines 35-40).

7. With respect to claim 4, Monforte discloses that the antibodies may comprise IgG immunoglobulins (column 7, lines 42-50).

8. With respect to claim 5, the solid support may comprise a silicon chip (column 12, lines 65-67), to which biological molecules are linked or contacted (column 12, lines 51-56).

9. With respect to claim 6, Monforte discloses that mass spectrometry may be used for detecting the proteins (column 30, lines 38-41).

10. With respect to claims 10, 11, Monforte discloses substrates comprised of glass (column 12, lines 56-65), which is a chromatographic resin.

11. With respect to claim 12, Monforte discloses that the method may comprise binding target proteins to phage displayed antibodies, followed by a wash step to remove unbound components, and then the bound proteins are then eluted and used infect host cells, wherein the aggregated expression of the different target proteins is detected (column 16, lines 25-45)

12. With respect to claim 15, Monforte further discloses a binding moiety such as an antibody attached to a solid support that captures the target protein (column 13, lines 55-65).

Art Unit: 1641

13. With respect to claim 19, Monforte discloses that detection methods may include electrochemical detection and fluorescent detection (column 4, lines 1-14).

14. With respect to claim 20, Monforte teaches multiplexed assays for determining protein levels within a sample (column 2, lines 40-45), wherein the proteins are derived from one or more cells (column 2, lines 55-63). In particular, Monforte teaches using simple purifying method in order to prepare the samples for analysis (column 32, lines 45-39). Monforte further discloses the steps of providing a binding moiety such as an antibody attached to a solid support to captures the target protein and then applying a second binding moiety containing a signal generating element then binds to the captured target protein (column 13, lines 55-65). The protein is then detected and quantitated (column 14, lines 1-8). After detection, an analysis module is used for compiling the data into a database containing a profile for each sample or each target polypeptide in a sample (column 37, lines 20-25).

15. With respect to claim 21, Monforte discloses that the target proteins may comprise recombinant proteins (claim 2).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monforte [US 7,091,046] in view of Hutchens et al. [US 2001/0014461].

With respect to claim 7, Monforte teaches multiplexed assays for determining protein levels within a sample (column 2, lines 40-45), wherein the proteins are derived from one or more cells (column 2, lines 55-63). Monforte further discloses a binding moiety such as an antibody attached to a solid support that captures the target protein and a second binding moiety containing a signal generating element then binds to the captured target protein (column 13, lines 55-65). The protein is then detected and quantitated (column 14, lines 1-8) using methods such as matrix-assisted laser desorption/ionization (MALDI) time of flight mass spectrometry (column 4, lines 5-10). Monforte does not teach the use of surface enhanced laser desorption/ionization.

Hutchens et al., however, disclose that surface-enhanced laser desorption/ionization (SELDI) such as surface enhanced neat desorption (SEND) (para. 0190) represents a significant advance over MALDI in terms of specificity, selectivity, and sensitivity (para. 0188).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to adapt the method of Monforte to use detection methods such as SELDI and SEND, in order to achieve better specificity, selectivity, and sensitivity.

18. With respect to claim 8, Hutchens et al. disclose applying a layer of energy absorbing material (matrix material) onto which the analyte (the target proteins of Monforte) is placed which absorb the desorbing energy (from the laser) and cause the analyte to be desorbed (para. 0190).

19. With respect to claim 9, Hutchens et al. discloses a support for surface-enhanced laser desorption/ionization (SELDI), more specifically, for surface enhanced neat desorption (SEND) (para. 0190).

20. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monforte [US 7,091,046] in view of Schwarz [Schwarz, Five-membered mercaptoheterocyclic ligands for thiophilic adsorption chromatography, 1996, J Mol Recog 9, 672-674].

With respect to claims 13 and 14, Monforte teaches antibodies attached to solid supports (column 13, lines 55-65), wherein the support comprises chromatographic resins such as glass (column 12, lines 56-65). Monforte fails to teach that the antibodies are attached by derivatizing the support with a capture molecule that binds to the antibodies, wherein the capture molecule is Protein A, Protein G, or a mercaptoheterocyclic ligand.

Schwarz, however, discloses that mercaptoheterocyclic ligands readily adsorb antibodies in a highly specific manner (p. 673, col.2, para. 3).

Therefore, one of ordinary skill in the art at the time of the invention would have been motivated to derivatize the support of Monforte, as taught by Schwarz, in order to ensure that the antibodies were properly attached to the support in a highly specific manner. This would thus prevent the likelihood of the antibodies from detaching from the support during the course of the assay, while also reducing the likelihood of nonspecific binding.

21. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Monforte [US 7,091,046] in view of Piasio et al. [US 4,098,876].

With respect to claim 16, Monforte discloses a step wherein a binding moiety such as an antibody attached to a solid support captures the target protein and a second binding moiety comprising a second antibody with a signal-generating element then binds to the captured target

Art Unit: 1641

protein (column 13, lines 55-65). Monforte fails to teach the step of first binding the target proteins in the sample to the labeled antibody, and then binding with the immobilized antibody.

Piasio et al, however, teach first immobilizing the sample containing the target proteins with a labeled antibody and then a second incubation with the immobilized antibody (column 3, lines 14-25), and further discloses that this allows for a higher assay sensitivity to be achieved and eliminates the need for an intermediate washing step (column 3, lines 28-33).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have first immobilizing the sample containing the target proteins with a labeled antibody and then a second incubation with the immobilized antibody in the method of Monforte, as suggested by Piasio et al., in order to obtain a higher assay sensitivity, and to reduce the complexity of the method by eliminating an intermediate washing step.

22. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monforte [US 7,091,046] in view of Piasio et al. [US 4,098,876], as applied to claim 16 above, and further in view of Hutchens et al. [US 2001/0014461] and Schwarz [Schwarz, Five-membered mercaptoheterocyclic ligands for thiophilic adsorption chromatography, 1996, J Mol Recog 9, 672-674].

With respect to claims 17 and 18, Monforte teaches antibodies attached to solid supports (column 13, lines 55-65), wherein the support comprises chromatographic resins such as glass (column 12, lines 56-65). Monforte fails to teach that the immobilized antibodies are attached by derivatizing the support with a capture molecule, wherein the capture molecule is Protein A,

Art Unit: 1641

Protein G, or a mercaptoheterocyclic ligand. Monforte also fails to teach that the solid support is a surface enhanced laser desorption/ ionization biochip.

Hutchens et al., however, disclose that surface-enhanced laser desorption/ionization (SELDI) such as surface enhanced neat desorption (SEND) (para. 0190) represents a significant advance over MALDI in terms of specificity, selectivity, and sensitivity (para. 0188).

Schwarz further discloses that mercaptoheterocyclic ligands readily adsorb antibodies in a highly specific manner (p. 673, col.2, para. 3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to adapt the method of Monforte to use detection methods such as SELDI and SEND, and utilize a surface enhanced laser desorption/ ionization biochip, in order to achieve better specificity, selectivity, and sensitivity.

One of ordinary skill in the art at the time of the invention would have further been motivated to derivatize the support of Monforte, as taught by Schwarz, in order to ensure that the immobilized antibodies were properly attached to the support in a highly specific manner. This would thus prevent the likelihood of the antibodies from detaching from the support during the course of the assay, while also reducing the likelihood of nonspecific binding.

Conclusion

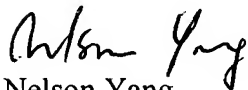
23. No claims are allowed.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Nelson Yang
Patent Examiner
Art Unit 1641